

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <div style="text-align: center; font-weight: bold; font-size: 1.2em;"> INFORMATION DISCLOSURE STATEMENT BY APPLICANT </div> <div style="text-align: center; font-style: italic; font-size: 0.8em;"> (Use as many sheets as necessary) </div>		<div style="text-align: center; font-weight: bold; font-size: 1.1em;"> Complete if Known </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/781,058</td> </tr> <tr> <td>Filing Date</td> <td>February 28, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>John Pafford et al.</td> </tr> <tr> <td>Art Unit</td> <td>3738</td> </tr> <tr> <td>Examiner Name</td> <td>David H. Willse</td> </tr> <tr> <td>Attorney Docket Number</td> <td>MSDI-455/PC263.33</td> </tr> </table>		Application Number	10/781,058	Filing Date	February 28, 2004	First Named Inventor	John Pafford et al.	Art Unit	3738	Examiner Name	David H. Willse	Attorney Docket Number	MSDI-455/PC263.33
Application Number	10/781,058														
Filing Date	February 28, 2004														
First Named Inventor	John Pafford et al.														
Art Unit	3738														
Examiner Name	David H. Willse														
Attorney Docket Number	MSDI-455/PC263.33														

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	7	WO 95/31947	11/30/1995	Spine-Tech, Inc.		✓
	8	EP 0 599 419 A2	06/01/1994	Bristol-Myers Squibb Co.		✓

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/781,058		
		Filing Date	February 18, 2004		
		First Named Inventor	John Pafford, et al.		
		Art Unit	3738		
		Examiner Name	David H. Willse		
Sheet	3	of	4	Attorney Docket Number	MSDI-455/PC263.33

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	CLOWARD, RALPH B., M.D. Honolulu, Hawaii. The Anterior Approach for Removal of Ruptured Cervical Disks. Presented at the meeting of the Harvey Cushing Society, Washington, D.C. April 22, 1958, pp. 602-617.	
	2	SMITH, GEORGE W. MD, ROBINSON, ROBERT A., MD. The treatment of Certain Cervical-Spine Disorders by Anterior Removal of the Intervertebral Disk and Interbody Fusion. The Journal of Bone and Joint Surgery. Vol. 40-A, No. 3, June 1958, pp. 607-624.	
	3	PRODUCT LITERATURE: Cage CR. Cervical-Spacing Cages." Scient'x, 10 et 7, Rue Duvivier 75007, Paris (date unknown).	
	4	PRODUCT LITERATURE: Cage CH. "Lumbar Spacing Cages." Scient'x, 10 et 7, Rue Duvivier 75007, Paris (date unknown).	
	5	PROCEEDINGS. 10th Annual Conf. North American Spine Society. Oct. 18-21, 1995. Washington, DC, pp. 10-11.	
	6	Stephen M. David, MD, et al., "Lumbar Spinal Fusion Using Recombinant Human Bone Morphogenetic Protein: A Randomized, Blinded and Controlled Study." American Academy of Orthopaedic Surgeons 1996 Annual Meeting-Scientific Program; Paper No. 74, February 22, 1996.	
	7	YAMAMURO, TAKAO, et al. Replacement of the Lumbar Vertebrae of Sheep w/Ceramic Prostheses. The Journal of Bone and Joint Surgery. Vol. 72-B, No. 5, Sept. 1990, pp. 889-893.	
	8	GERHART, TOBIN N., M.D., et al. Healing Segmental Femoral Defects in Sheep Using Recombinant Human Bone Morphogenetic Protein. Clinical Orthopaedics and Related Research, No. 293, pp. 317-326, August 1993.	
	9	PRELIMINARY PROGRAM. Forty-Second Annual Meeting of the Orthopaedic Research Society. Hyatt Regency, Atlanta, Georgia, February 18-22, 1996.	
	10	MUSCULOSKELETAL TRANSPLANT FOUNDATION. EndoDowel, October, 1996.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/781,058
		Filing Date	February 18, 2004
		First Named Inventor	John Pafford et al.
		Art Unit	3738
		Examiner Name	David H. Willse
Sheet 4	of 4	Attorney Docket Number	MSDI455-PC263.33

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	11	Marcus F. Sciadini, MD, et al., "Evaluation of Recombinant Human Bone Morphogenetic Protein-2 With a Collagen Carrier in a Canine Segmental Defect Model: Dose Response and Long-Term Results." Amer. Acad. of Orthopaedic Surg. 1996 Annual Meeting-Scientific Program; Paper No. 75. February 22, 1996.	
	12	MUSCULOSKELETAL TRANSPLANT FOUNDATION. Quality Must be First Priority. Marketing materials of Depuy Motech. April, 1996.	
	13	SIMMONS, J.W. Bone Banking. Lumbar Spine Surgery: Techniques and Complications. A. White and T. Rothman, eds. pp. 459-470. Mosby, St. Louis, 1987.	
	14	UNILAB, INC. Unilab Surgibone. 100,000 Implants. TUV Product Service. Product profile. Unilab, Inc., Hillside, NJ. (date unknown).	
	15	ALBEE, F.H. et al. Bone Graft Surgery in Disease, Injury and Deformity. D. Appleton-Century Company, Inc. (publisher), 1940. pp. xi-xv; 1-31; 48-107; and 210-227.	
	16	VICH, J.M.O., MD. Anterior cervical interbody fusion with threaded Cylindrical bone. Journal of Neurosurgery, Vol. 63, pp. 750-753, November, 1985.	
	17	VICH, J.M.O., MD. Update on the Cloward procedure: new instruments. Journal of Neurosurgery, Vol. 81, pp. 716-720, November, 1994.	
	18	SOFAMOR DANEK. Sofamor Danek Laparoscopic Bone Dowel System Laparoscopic Surgial Procedure. Laparoscopic Bone Dowel Surgical Technique. 1995.	
	19	SOFAMOR DANEK. Laparoscopic Bone Dowel Instruments. Product information. 1995.	
	20	MUSCULOSKELETAL TRANSPLANT FOUNDATION. Vertigraft Serrated Bone Sections. Product information. Depuy Motech. (date unknown).	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.